

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

5
SYSTEMS USED IN PERFORMING FEMORAL
AND TIBIAL RESECTION IN KNEE SURGERY

BACKGROUND OF THE INVENTION

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1. Prior Provisional Application

C17 This application relates to and claims priority
from a pending provisional application Serial Number
_____ entitled "Methods, Systems and Tools Used
15 In Performing Femoral and Tibial Resection In Knee
Surgery", filed February 28, 2001.

2. Field of the Invention

20 The invention generally relates to systems that
may be used in performing joint surgery; with a
particular embodiment of the invention being described,
without limitation, in the context of knee arthroplasty.
More particularly, with respect to knee arthroplasty, the
invention relates to systems used to properly locate and
25 guide instruments that resect bone in order to achieve a
proper cut; and facilitate the proper location and
installation of artificial femoral and tibial prosthetic
components.

3. Brief Description Of The Prior Art

Total knee arthroplasty involves the replacement of portions of the patellar, femur and tibia with artificial components. In particular, a proximal portion of the tibia and a distal portion of the femur are cut away (resected) and replaced with artificial components.

As used herein, when referring to bones or other body parts, the term "proximal" means closest to the heart and the term "distal" means more distant from the heart. When referring to tools and instruments, the term "proximal" means closest to the practitioner and the term "distal" means distant from the practitioner.

There are several types of knee prostheses known in the art. One type is sometimes referred to as a "resurfacing type". In these prostheses, the articular surface of the distal femur and proximal tibia are "resurfaced" with respective metal and plastic condylar-type articular bearing components.

The femoral component is typically a metallic alloy construction (cobalt-chrome alloy or 6Al4V titanium alloy) and provides medial and lateral condylar bearing surfaces of multi-radius design of similar shape and geometry as the natural distal femur or femoral-side of the knee joint.

One important aspect of these procedures is the correct resection of the distal femur and proximal tibia. These resections must provide planes which are correctly angled in order to properly accept the prosthetic components. In particular, the resection planes must be correctly located relative to three parameters: proximal-distal location, varus-valgus angle and flexion-extension angle.

U.S. Patent 5,916,219 (hereby incorporated by reference) discloses an apparatus and method for tibial alignment which allows the independent establishment of two separate geometric planes to be used as a reference for the cutting of the tibial plateau during total knee arthroplasty.

Two separate frame assemblies with telescoping rods are attached to the tibia with a fixed relative angle between them, thereby allowing alignment with the mechanical axis of the bone. A cutting block is mounted on one of the assembly frames and is positioned against the tibia. Stabilizing pins are then placed in the cutting block, allowing the proper tibial plateau resection plane to be created.

5 The apparatus and method taught in the '219
patent, while solving many prior art problems as
indicated therein, has a few disadvantages. The
alignment apparatus must be removed prior to performing
resection. The device ratchets to discrete locations,
preventing a smooth (hereinafter defined as an
"infinitely adjustable") alignment. Further, the device
can only be used to resect the tibia and cannot be used
for femoral resection.

10 Recently, various computerized systems have
been introduced to aid the practitioner during different
surgical procedures. A typical, commercially available
system is described in the attached Appendix. Such
systems typically include multiple video cameras which
are deployed above and around the surgical site; and a
plurality of dynamic reference frame (DRF) devices, also
known as trackers, which are attached to body parts and
surgical instruments.

20 The trackers are generally LED devices which
are visible to the cameras. Using software designed for
a particular surgical procedure, a computer receiving
input from the cameras guides the placement of surgical
instruments.

5 The prior art instruments used for determining
the correct planes for tibial and femoral resection in
total knee arthroplasty are not well suited for use with
computerized systems. The known tools utilize either
intra-medullary alignment or extra-medullary alignment
techniques and movement in three degrees of freedom is
difficult or impossible. Moreover, in order to be useful
with computer aided navigation systems, trackers must be
10 attached to the tools. Existing tools do not permit or
readily facilitate the attachment of trackers.

Although computer aided navigation systems are
superior to unaided visual navigation by the
15 practitioner, computers have known faults. As every
computer user knows, any computer can crash or fail
in such a way that it may take hours to repair. This is
unacceptable during a surgical procedure. Therefore, it
is necessary to provide a backup system of some kind so
20 that the procedure may be completed without the failed
computer.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to
5 provide methods, systems and tools for performing femoral
and tibial resection and indeed, methods, systems and
tools similarly useful in performing surgery on other
joints (implicit in the objectives and description of the
invention set forth herein, although reference to the
10 femur and tibial resection is specifically made for the
sake of illustration).

It is also an object of the invention to
provide methods, systems and tools for femoral and tibial
15 resection which allow location of a cutting guide
relative to three parameters.

It is another object of the invention to
provide methods, systems and tools for femoral and tibial
20 resection which are infinitely adjustable.

It is still another object of the invention to
provide methods, systems and tools for femoral and tibial
resection which are adapted to be used with computer
25 aided navigation systems.

It is also an object of the invention to
provide tools which can be used for both femoral and
tibial resection.

It is another object of the invention to provide methods, systems and tools for femoral and tibial resection which can be used without computer aided navigation systems should such a system fail during surgery.

In accord with these objects which will be discussed in detail below, the tools of the present invention (again, described in the context of knee surgery for illustrative purposes only), include anchoring devices for attachment to the femur and the tibia, a three-way alignment guide attachable to the anchoring devices and adjustable relative to three parameters, two embodiments of a resection guide attachable to the alignment guide and equipped with couplings for trackers, a plane probe for examining the resected plane, and apparatus for EM alignment of the resection guide in the event of a computer failure.

According to one aspect of the invention, the tibial anchoring device is specially designed to fit the triangular anatomy of the tibia. According to further aspects of the invention, the two resection guides both include rotatable pin guides to allow selection of anchoring pin location; one resection guide may be slotted and according to another embodiment of the invention, one is not slotted.

Further, according to one embodiment of the invention, the apparatus for visual EM alignment includes an EM rod and an EM alignment guide (sometimes referred to as an alignment handle). The EM rod is attachable to the EM alignment guide and the EM alignment guide is attachable to the cutting guide. The EM alignment guide contemplated by a further aspect of the invention has two ends, one of which is adapted for femoral alignment and the other of which is adapted for tibial alignment.

The methods of the invention include operating the computer aided navigation apparatus in the conventional manner including attaching one or more trackers to the bone to be resected; choosing a location for the anchoring device with or without guidance from the computer and installing the anchoring device; attaching the three-way alignment guide to the anchoring device; attaching a resection guide to the alignment guide; attaching one or two trackers to the resection guide; locating the resection guide with the aid of the alignment guide and the computer; fixing the resection guide to the bone with pins through the rotatable pin guides; and resecting the bone.

After the bone is resected, the resection plane probe may be attached to a tracker and moved about the resected plane to obtain feedback from the computer navigation system.

In the event of computer failure, the methods include attaching the EM alignment guide to the resection guide; attaching the EM rod to the EM alignment guide; and locating the resection guide by visual location of the EM rod rather than by feedback from the computer navigation system.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a broken perspective view of the distal femur with an anchoring device according to the invention;

FIG. 2 is a side elevational view of the anchoring device installed in the distal femur;

FIG. 3 is a perspective view of the anchoring device installed in the distal femur with a three-way alignment guide according to the invention not yet attached to the anchoring device;

FIG. 4 is a view similar to FIG. 3 showing the alignment guide attached to the anchoring device;

FIG. 5 is a perspective view showing a first embodiment of a resection guide according to the invention not yet attached to the three-way alignment guide;

FIG. 6 is a perspective view showing a first embodiment of a resection guide according to the invention attached to the three-way alignment guide;

5 FIG. 7 is a side elevational view showing a first embodiment of a resection guide according to the invention attached to the three-way alignment guide;

10 FIG. 8 is a perspective view showing a second embodiment of a resection guide according to the invention attached to the three-way alignment guide;

15 FIG. 9 is a perspective view of a resection plane probe according to the invention;

FIG. 10 is a perspective view of a tibial anchoring device according to the invention;

20 FIG. 11 is a perspective view of a fail safe EM alignment guide according to the invention;

25 FIG. 12 is a perspective view of an extra medullary alignment rod for use with the EM alignment guide shown in Figure 11; and

FIG. 13 is a side elevational view of the fail safe EM alignment guide attached to the resection cutting guide with the EM rod attached to the EM alignment guide.

BRIEF DESCRIPTION OF THE APPENDIX

The attached ten page Appendix describes the parts and assembly of a computer navigation system suitable for use with the invention. The described parts are commercially available and may be assembled by those skilled in the art according to the assembly instructions, incorporated herein by reference.

DETAILED DESCRIPTION

Turning now to the Figures, the apparatus of the invention will be best understood by a description of the methods of the invention with reference to the Figures.

As shown in Figures 1 and 2 an anchoring device 10 is installed in the bone 1 in a region proximal to the lateral anterior cortex and within the incision. The location for the anchoring device may be chosen by eye or with the aid of the tracking/navigation software. As shown in the Figures, the anchoring device 10 is a pin which is screwed into the bone. Other anchoring devices such as plates could be used, however.

With the anchoring device 10 in place, the alignment guide 12 is lowered on to it as shown in Figures 3-5.

As seen best in Figure 5, the alignment guide 12 has three cam locks (or equivalent means for releasably locking) 12a, 12b, 12c. The cam lock 12a allows the alignment guide to be adjusted according to varus-valgus angle relative to the anchoring device 10. The cam lock 12b allows the alignment guide to be adjusted according to flexion-extension angle relative to the anchoring device 10. The cam lock 12c opens the end of the alignment device to receive the resection guide 14 shown in Figures 5-7.

Anoa2 > Referring now to Figures 5-7, the exemplary depicted resection guide 14 has a cutting guide surface 14a, an attachment rod 14b, a pair of connectors 14c, 14d for connecting trackers (not shown), a pair of rotatable pin guides 14e, 14f, and a pair of fail safe mounting bores 14g, 14h.

The resection guide 14 is attached to the alignment guide 12 by opening cam lock 12c and inserting the attachment rod 14b into the alignment guide. It will be appreciated by those skilled in the art that the cam lock 12c allows proximal-distal positioning of the resection guide 14. After the resection guide 14 is attached to the alignment device 12, a tracker is attached to the guide 14.

With the tracker attached, the first cam lock 12a is opened and the resection guide is moved in the varus-valgus plane until the navigation software indicates the proper alignment. The cam lock 12a is then locked.

Cam lock 12b is unlocked and the resection guide is moved in the flexion-extension plane until the navigation software indicates the proper alignment. The cam lock 12b is then locked. The order of performing the aforementioned steps of unlocking and relocking either or both of cam locks 12a and 12b, may be decided by the surgeon.

Lastly, the cam lock 12c is opened and the resection guide is positioned in the proximal-distal plane until the navigation software indicates the proper alignment. The cam lock 12c is then locked. With the resection guide properly located, it may be affixed to the bone with pins (not shown) via the rotatable pin guides 14e, 14f. The pin guides are rotatable so that the practitioner may choose the best site for inserting a pin. The next step in the procedure is to resect the distal end of the femur using the resection guide 14.

Those skilled in the art will appreciate that if the anchor pin 10 is not substantially perpendicular to the varus-valgus plane, the steps may need to be repeated to tune out error introduced by the misaligned anchor pin. One possible solution is to install the pin with a drill having an attached tracker thereby allowing the navigation software to guide the placement of the pin.

Figure 8 illustrates an alternate embodiment of a resection guide 114. The resection guide 114 is identical to the resection guide 14 except that it has a slot 114a for the cutting tool (not shown). Some practitioners prefer slotted cutting guides and others prefer non-slotted guides.

After the distal femur is resected, the accuracy of the cut can be checked using the resection plane probe 16 shown in Figure 9. The probe 16 has a smooth planar surface 16a and a coupling 16b for attaching a tracker. With a tracker attached to the probe, it is moved about the resected surface and the navigation software determines the accuracy of the resection.

All of the procedures described above can now be repeated to resect the proximal end of the tibia. Due to the triangular shape of the tibia, a special anchoring device 18, shown in Figure 10, is used.

The anchoring device 18 has an anchoring post 18a for attaching the alignment guide, an angled body 18b, a side slot 18c, and a slot clamp 18d. The anchoring device 18 is attached to the tibia by inserting a pin through the slot 18c into the medial side of the tibia in a region within the incision and distal to the tibial tubercle. The clamp 18d is closed to clamp the slot 18c relative to the pin (not shown).

It will be appreciated by those skilled in the art that the slot 18c has a plurality of grooves to snugly grab the pin. With the anchoring device 18 in place, the procedure described above is repeated to resect the proximal tibia.

Although the computerized navigation systems are a major advance in arthroplasty, computers often fail and at most inopportune times. The present invention provides a fail safe back up system for use when a computerized navigation system fails.

Referring now to Figures 11-13, the invention provides a manual EM alignment guide 20 and an EM alignment rod 22. The guide 20 includes a mounting shaft 20a, two bores 20b, 20c for receiving the EM rod, a femur guide 20d and a tibia guide 20e.

The mounting shaft 20a is inserted into one of the fail safe bores (14g, 14h in Figure 5) of the resection guide 14 and the EM rod 22 is inserted into one of the bores 20b, 20c in the guide 20. When used with the femur, the EM rod 22 is inserted through the bore 20c and the femur guide 20d is placed against the distal end of the femur as shown in Figure 13. Flexion-extension and varus-valgus positioning may then be accomplished visually using the EM rod. For use with the tibia, the EM rod is placed on the other bore and the tibia guide is placed against the proximal tibia.

There have been described and illustrated herein methods and tools for resection of the distal femur and proximal tibia. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise.

For example, as indicated hereinbefore, the first two positioning steps may be reversed in sequence, provided that the navigation software is suitably
5 modified. Moreover, the clamps on the alignment guide need not be cam locks, but could be other types of clamps.

10 Although the apparatus has been described as three separate pieces (the anchor, the alignment guide, and the resection guide), it could be two pieces or a single piece. If it were a single piece, it will be appreciated that separate devices would preferably be provided for tibia and femur.

15 In general, as previously indicated, the methods and tools of the invention could be used with other joints other than the knee. It is believed that the methods and tools could be used in arthroplasty of
20 the hip, shoulder, elbow, etc.

It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its
25 spirit and scope as so claimed.